SLOVENSKI STANDARD

SIST EN ISO 21534:2008

01-april-2008

Nadomeġļ a:

SIST EN 12010:2000

Neaktivni kirurški vsadki (implantati) - Sklepne proteze - Posebne zahteve (ISO 21534:2007)

Non-active surgical implants - Joint replacement implants - Particular requirements (ISO 21534:2007)

Nichtaktive chirurgische Implantate - Implantate zum Gelenkersatz - Besondere Anforderungen (ISO 21534:2007)

Implants chirurgicaux non actifs - Implants de remplacement d'articulation - Exigences particulieres (ISO 21534:2007)

Ta slovenski standard je istoveten z: **EN ISO 21534:2007**

ICS:

11.040.40

SIST EN ISO 21534:2008 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21534

September 2007

ICS 11.040.40

Supersedes EN 12010:1998

English Version

Non-active surgical implants - Joint replacement implants - Particular requirements (ISO 21534:2007)

Implants chirurgicaux non actifs - Implants de remplacement d'articulation - Exigences particulières (ISO 21534:2007)

Nichtaktive chirurgische Implantate - Implantate zum Gelenkersatz - Besondere Anforderungen (ISO 21534:2007)

This European Standard was approved by CEN on 16 August 2007.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

This document (EN ISO 21534:2007) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 285 "Non-active surgical implants", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2008, and conflicting national standards shall be withdrawn at the latest by March 2008.

This document supersedes EN 12010:1998.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

For relationship with EC Directive(s), see informative Annex ZA which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 21534:2007 has been approved by CEN as a EN ISO 21534:2007 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this International Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2, 3, 4, 5, 7.1, 7.2, 9.2	
5	1, 2, 3, 4, 5, 6, 7.1, 9.1, 9.2	
6	1, 2, 3, 4, 7.1, 7.2, 7.3, 7.4, 8.2, 9.1, 9.2	
7	1, 2, 3, 4, 5, 6, 7.1, 7.2, 7.3, 14	
8	1, 2, 3, 4, 5, 7.1, 7.2, 7.3	
9	3, 8.1, 8.3, 8.4, 8.5, 8.6, 8.7, 13.3	
10	3, 5, 7.2, 8.1, 8.3, 8.4, 8.5, 8.6, 8.7	
11	9.1, 13	
NOTE All clauses supplement and are dependent on the corresponding clauses of EN 14630		

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 21534

Second edition
2007-10-01

Non-active surgical implants — Joint replacement implants — Particular requirements

Implants chirurgicaux non actifs — Implants de remplacement d'articulation — Exigences particulières

Reference number
ISO 21534:2007(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 21534 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

This second edition cancels and replaces the first edition (ISO 21534:2002), which has been technically revised.